REMARKS

Claim 1 remains in its previously presented form in light of the agreements reached during an in-person interview conducted on January 25, 2011. Claims 2, 14, 27, 29, 43, 46, and 60 have been amended. Written description support for these amendments is found throughout the original specification. No new matter has been added. Applicant respectfully submits that all pending claims 1-6, 8-10, and 14-60 are in condition for allowance.

Examiner Interview

The Applicant thanks the Examiner for participating in the in-person interview on January 25, 2011, during which the drawing objection, the § 112 rejections, and the § 103 rejections were discussed. For the reasons described below, **it was agreed** that the drawing objection would be withdrawn in light of FIGS. 1 and 4 (illustrating two instruments 20 and 22) and the original specification at page 24 (teaching an example cannula/insertion instrument configuration for the two instruments 20 and 22). Also, **it was agreed** that the §112 rejection would be withdrawn for the reasons described in detail below. Regarding the § 103 rejection based upon Neubardt (US 5,474,558) in view of the Calancie article, Raymond (US 5,284,153), and Katims (US 5,806,522), **it was agreed** that the Calancie article does not disclose the claimed "detecting an onset neuro-muscular response having *an amplitude greater than a predetermined positive value*." Likewise, **it was agreed** that the Katims reference does not expressly or inherently disclose a method step of "displaying on an integrated display device of said neurophysiology system *while viewed by a surgeon operating on the patient's spine* an onset electrical stimulus current level . . . ."

Drawings

The Office Action objected to the drawings because they purportedly failed to show the claimed instrument inserted through the cannula (as described in claims 2, 29, and 46. *See* Office Action at p. 2. The Applicant respectfully traverses this objection. **As agreed during the January 25 interview**, the teachings of FIGS. 1 and 4 (showing instruments 20 and 22) and the original specification at page 24 (describing the option for instrument 22 to be a probe inserted

through the instrument 20 in the form of a "cannula") are more than sufficient support. *See* Original Specification at FIGS. 1 and 4; page 24, lines 4-6. Accordingly, the objection to the drawings was improper, and the Applicant respectfully requests withdrawal of the objection to the drawings.

Compliance with 35 U.S.C. § 112

Claims 1, 14, 27, 28, 43, 44, and 60 were rejected under 35 USC § 112, ¶1 for lack of enablement. More specifically, the Office Action relied upon an assertion that the human *nerve* tissue has a "[r]esting potential" in the range of -60 to -80 microvolts:

> Resting potential of the membrane is normally in the range of -60 mV to -80 mV. A predetermined value (threshold) in the range of 60-80 mV would yield the zero potential of the axon. The current specification fails to disclose if the predetermined value of 60 mV to 80 mV is a value different from the zero potential of the axon (for instance a value of the positive potential), or if the 60 mV to 80 mV range is in fact the zero potential of the axon.

See Office Action at p. 3. During the January 25 interview, the Examiner clarified that he was referring to the resting potential of the *nerve* tissue, not the leg *muscle* tissue. Applicant explained that original specification teaches that the neuro-muscular response signal is detected in the leg muscles:

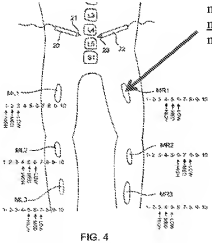

FIG. 4

As agreed during the January 25 interview, the §112, ¶1 rejection of claims 1, 14, 27, 28, 43, 44, and 60 was improper because the purported "resting potential" of the nerve

membrane near the spine would not raise the "zero potential of the axon" issue specified in the Office Action due to the fact that the claimed monitor detects muscular responses in the *muscle* myotomes. Simply put, this §112 rejection of claims 1, 14, 27, 28, 43, 44, and 60 was based upon an assertion (the value of the resting potential of the nerve tissue) that is not relevant to the claimed method. Therefore, the §112, ¶1 rejection was improper, and the Applicant respectfully requests withdrawal of this § 112 rejection.

Regarding the §112, ¶2 rejections of dependent claims 2, 29, and 46, it was agreed during the January 25, 2011 interview that the phrase "at least one of" in these claims would be removed. Claims 2, 29, and 46 have been amended in the agreed manner. Accordingly, the Applicant respectfully requests withdrawal of the rejections under §112, ¶2.

Claims 1-6, 8-10, 18-26, and 28

Independent claim 1 and particular dependent claims were rejected under 35 U.S.C. § 103 as being unpatentable over Neubardt in view of Calancie in further view of Raymond and in further view of Katims. Applicant respectfully submits that even if there was an articulated reason that would have prompted a skilled artisan to combine these references as proposed in the Office Action (an issue that is not conceded herein), the proposed combination would nevertheless fail to achieve the method set forth in amended claim 1.

First, **as agreed during the January 25 interview**, the proposed combination of Neubardt, Calancie, Raymond, and Katims would fail to achieve a method step of "*detecting an onset neuro-muscular response having an amplitude greater than a predetermined positive value in response to the application of said electrical stimulus* to said first aspect of said bone by automatically increasing said electrical stimulus in constant increments until said onset neuro-muscular response is detected by one or more of the EMG sensor electrodes, wherein said automatic increasing is controlled by said neurophysiology system." The Office Action contends that the Calancie reference discloses this claim element based upon the same erroneous reasoning of the "resting potential" of the nerve tissue (as described above in the analysis of the § 112, ¶1 rejection). *See* Office Action at pp. 6-7. According to the Office Action, Calancie discloses that the neurophysiologist examines the EMG waveform having any amplitude greater than 0, but this threshold is not "an amplitude value greater than a predetermined *positive* value."

The Office Action contends that (as explained by the Examiner during the January 25 interview) the claimed predetermined positive value is actually zero because it would be offset by the "resting potential" of the *nerve* tissue. As previously described, the claimed method electrically monitors the leg *muscle* tissue, not the *nerve* tissue. Here again, the claim rejection was based upon an assertion (the value of the resting potential of the nerve tissue) that is not relevant to the claimed method. For at least this reason, the §103 rejection of claim 1 and its dependent claims was improper, and the Applicant respectfully requests withdrawal of this § 103 rejection based upon Neubardt in view of Calancie, Raymond, and Katims.

Second, **as agreed during the January 25 interview**, the Office action erred in concluding that the Katims references discloses the step of "displaying on an integrated display device of said neurophysiology system *while viewed by a surgeon operating on the patient's spine* an onset electrical stimulus current level which causes said onset neuro-muscular response." The Office Action contends that Katim's disclosure of possibly using the monitor "intraoperatively" (col. 34) discloses this claimed step:

> Alternatively, physiological measures may be ascertained using the present invention. However, this may only be conducted in conjunction with physiological monitoring to measure physiological responses to the electrical stimulation. This may be incorporated, for example, intraoperatively in surgery in assessing sensory function in patients suffering from intractable pain and other neuropathological conditions such as syringomyelia. The information obtained by the clinician in monitoring peripheral nerve cells responses to this type of electrical stimulus that is standardized is valuable for prognostic purposes and in guiding the surgeon as to which nerve tissue is pathological for biopsy purposes, ablation purposes and for pharmaceutical treatment purposes, as well as electrical stimulation for therapeutic application purposes.

Katims does not *expressly disclose* the claimed step.

Further, nothing in Katims discloses that that Katims's monitoring system is necessarily (inherently) viewed by the surgeon, rather than the traditional method of being viewed by a neurophysiologist (as taught by Calancie).

See Katims at col. 34, lines 9-23. This is not enough. As agreed during the January 25 interview, Katims does disclose not a method in which it is "necessarily present" (the standard under MPEP § 2112 for inherency) that the monitor should be viewed by the surgeon rather than a neurophysiologist (as disclosed by Calancie). Simply put, Katims limited and terse teaching is not enough to disclose or suggest Applicant's claimed method step. For this reason alone, the

§103 rejection of claim 1 and its dependent claims was improper, and the Applicant respectfully requests withdrawal of this § 103 rejection based upon Neubardt in view of Calancie, Raymond, and Katims.

Finally, the Applicant submits that it would not have been obvious at the time of the invention to achieve Applicant's claimed method. For example, the Applicant disagrees with any contention that it would have been obvious to use Katims system "intraoperatively" in a manner that "display[s] on an integrated display device of said neurophysiology system *while viewed by a surgeon operating on the patient's spine* an onset electrical stimulus current level which causes said onset neuro-muscular response." Such a contention would be clearly erroneous and "contrary to accepted wisdom in the art." *See* MPEP § 2143.(X)(D)(3). For example, the Calancie reference expressly teaches away from such a method by explaining that the intraoperative neuromoniting data is viewed by a "electrophysiologist" who then verbally communicates with the surgeons as needed. *See* Calancie at p. 2782, left column. Indeed, numerous other references provide objective evidence of the then-common understanding that using a separate neurophysiologist (or a similarly qualified technician who is not performing the surgical procedure) to view the neuromonitoring data was the recommended practice for purposes of "patient safety":

- *See* ASET, *American Society of Electroneurodiagnostic Technologists Position Statement on Unattended Intraoperative Neurophysiologic Monitoring*, p. 1 (2007), available at http://www.aset.org/files/public/Position_Statement_on_Unattended_Monitoring.pdf:

  > ***In the best interest of patient safety***, ASET strongly recommends the utilization of qualified Neurodiagnostic/Neuromonitoring personnel during ***all*** interoperative Neuromonitoring procedures.

- *See* Zouridakis et al., A CONCISE GUIDE TO INTRAOPERATIVE MONITORING, p. 5 Section 1.9 (CRC Press 2001):

  > Typically, one person (***a clinical neurophysiologist***) is responsible for several operating rooms, while a technologist is available in each room to place electrodes, setup equipment, and monitor the case during the less critical phases of an operation. This is similar to how anesthesia teams are organized in most institutions. All personnel involved with monitoring should be able to interpret the recordings and communicate the findings to the surgeons. . . . This implies that at least ***the person responsible for monitoring, in addition to being able to troubleshoot and solve problems with equipment, should have a strong background in clinical neurophysiology*** . . . .

Based upon this objective evidence, a person of ordinary skill in the art at the time of Applicant's invention would not have ignored the ordinary customs and then concluded from the proposed combination Neubardt in view of Calancie, Raymond, and Katims that the resulting method should include all of the claimed elements. MPEP § 2145(X)(D)(3) (stating that "[t]he totality of the prior art must be considered, and ***proceeding contrary to accepted wisdom in the art is evidence of nonobviousness***"). Given this objective evidence and the lack of disclosure in the cited references, then "[i]t is difficult but necessary that the decisionmaker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made . . . , to occupy the mind of one skilled in the art who is presented only with the references, and ***who is normally guided by the then-accepted wisdom in the art***." *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1552-53 (Fed. Cir. 1983). This mindset is required to avoid "fall[ing] victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *Id.*

For any of the aforementioned reasons, the proposed combination of Neubardt, Calancie, Raymond, and Katims would necessarily fail to achieve all elements of the method set forth in claim 1 even if there was an articulated reason that would have prompted a skilled artisan to combine these references (which there is not). Applicant respectfully submits that claim 1 is patentable over the prior art of record. Dependent claims 2-6, 8-10, 18-26, and 28 are patentable for at least the same reasons as claim 1 and for the additional inventive combination recited therein.

Claims 14-17, 26, and 29-44

Independent claim 14 and particular dependent claims were rejected under 35 U.S.C. § 103 as being unpatentable over Neubardt in view of Calancie in further view of Raymond and in further view of Katims. Applicant respectfully submits that the proposed combination would fail to achieve all elements of the method set forth in amended claim 14.

First, **as agreed during the January 25 interview**, the proposed combination of Neubardt, Calancie, Raymond, and Katims would fail to achieve a method in which "said onset neuro-muscular response is detected by one or more of the EMG sensor electrodes outputting an EMG signal having *an amplitude value greater than a predetermined positive value.* As previously

described in the analysis of claim 1, the Office Action erred when concluding the Calancie discloses this claimed feature.

Second, **for the reasons similar to those described in connection with claim 1 (and discussed during the January 25 interview)**, the proposed combination of Neubardt, Calancie, Raymond, and Katims would fail to achieve a method that includes "visually displaying to said surgeon, *in response to determining said onset neuro-muscular response,* an electrical current value representing said onset electrical stimulus current level causing said onset neuro-muscular response for said spinal nerve."

For any of these reasons, the proposed combination of Neubardt, Calancie, Raymond, and Katims would nevertheless fail to achieve the method set forth in claim 14 even if there was an articulated reason that would have prompted a skilled artisan to combine these references as proposed in the Office Action (which there is not). Applicant respectfully submits that claim 14 is patentable over the prior art of record. Dependent claims 15-17, 26, and 29-44 are patentable for at least the same reasons as claim 14 and for the additional inventive combination recited therein.

Claims 27 and 45-60

Independent claim 27 and particular dependent claims were rejected under 35 U.S.C. § 103 as being unpatentable over Neubardt in view of Calancie in further view of Raymond and in further view of Katims. Applicant respectfully submits that the proposed combination would fail to achieve all elements of the method set forth in amended claim 27.

First, **as agreed during the January 25 interview**, the proposed combination of Neubardt, Calancie, Raymond, and Katims would fail to achieve a method in which "said onset neuro-muscular response is detected by one or more of the EMG sensor electrodes outputting an EMG signal having *an amplitude value greater than a predetermined positive value*, wherein said amplitude value greater than the predetermined positive value comprises a peak-to-peak amplitude value greater than the predetermined positive value." As previously described in the analysis of claim 1, the Office Action erred when concluding the Calancie discloses this claimed feature.

Second, the proposed combination of Neubardt, Calancie, Raymond, and Katims would fail to achieve a method step of "*in response to determining said onset neuro-muscular response,*

displaying on a display device of said neurophysiology system that is viewable by a surgeon operating on the patient's spine an onset electrical stimulus current level which causes said onset neuro-muscular response."

For any of these reasons, the proposed combination of Neubardt, Calancie, Raymond, and Katims would nevertheless fail to achieve the method set forth in claim 27 even if there was an articulated reason that would have prompted a skilled artisan to combine these references as proposed in the Office Action (which there is not). Applicant respectfully submits that claim 27 is patentable over the prior art of record. Dependent claims 45-60 are patentable for at least the same reasons as claim 27 and for the additional inventive combinations described therein.

Request for Reconsideration

Applicant submits that claims 1-6, 8-10, and 14-60 are patentable over the prior art of record. Reconsideration and allowance is respectfully requested. ***In the event that no Notice of Allowance will be provided in the next communication, Applicant respectfully requests that the Examiner telephones the undersigned attorney prior to the next communication so that prosecution on the merits may be expedited.***

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the claim amendments herein do not signify concession of unpatentability of claims 2, 14, 27, 29, 43, 46, and 60 prior to the amendments herein. Applicant hereby specifically reserves the right to prosecute the previously presented subject matter of claims 2, 14, 27, 29, 43, 46, and 60 (prior to the amendment herein) in a continuation application. Applicant hereby specifically reserves the right to prosecute claims of different or broader scope in a continuation application. The Patent Office should infer no (i) adoption of a position with respect to patentability, (ii) change in the Applicant's position with respect to any claim or subject matter of the invention, or

(iii) acquiescence in any way to any position taken by the Office Action, based on amendments made herein.

The Amendment is submitted with a Petition for Extension of Time and the requisite fee. No other fees are believed to be due at this time. If necessary, please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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